

**510(k) Summary
for Mission Diagnostic Reagents on AVL
98X AVL Electrolyte Analyzers**

K013850

1. Submitter's Name & Address

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:

Linda Stundtner
QA/RA Coordinator
508-429-0450

Establishment Registration Number: In Process

Date of Preparation:

November 16, 2001

2. Identification of the Device:

| | |
|-------------------------|---|
| Proprietary/Trade name: | Standard A, Standard B, Standard C, Cal, Slope |
| Common or usual name | Calibrators for ISE and/or pH/Blood Gas automated systems |
| Classification name: | Calibrator, secondary |
| Device Classification | II |
| Regulation Number: | 21 CFR § 862.1150 |
| Panel: | Chemistry (75) |
| Product Code: | JIT |

3. Predicate Device:

Mission claims substantial equivalence to the AVL Calibrators listed below:

| Mission Product | AVL Equivalent |
|------------------------|-----------------------|
| AV-BP0936D Standard A | BP0936 Standard A |
| AV-BP0937D Standard B | BP0937 Standard B |
| AV-BP0938D Standard C | BP0938 Standard C |
| AV-BP0442D Standard B | BP0442 Standard B |
| AV-BP1232D Standard A | BP1232 Standard A |
| AV-BP1218D Standard B | BP1218 Standard B |
| AV-BP1203D Standard A | BP1203 Standard A |
| AV-BP1201D Standard B | BP1201 Standard B |

4. Device Description:

The Calibrators for the AVL Electrolyte Instruments are aqueous reagents with salts added to obtain desired analyte levels to provide calibration of the electrodes and rinse the sample path.

5. Intended Use:

The reagents are intended for use on equivalent AVL Electrolyte Instruments. AVL is the original equipment manufacturer (OEM) of the instruments and the predicate reagents which are necessary for the continued operation and use of the instruments.

The Mission reagents are intended to serve as direct replacements to like named products manufactured by AVL.

| | Reagent Used on Instrument | | | | | | | | Analytes Measured | | | | | | |
|----------------|----------------------------|--------|--------|--------|--------|--------|--------|--------|-------------------|---|----|----|----|------------------|----|
| AVL Instrument | BP0936 | BP0937 | BP0938 | BP0442 | BP1232 | BP1218 | BP1203 | BP1201 | Na | K | Cl | Ca | Li | tCO ₂ | pH |
| 982 | X | | | X | | | | | X | X | | | | | |
| 983 | X | | | X | | | | | X | X | X | | | | |
| 984 | | | | | X | X | | | X | X | | X | | | |
| 985 | X | X | X | | | | | | X | X | | | X | | |
| 986 | | | | | | | X | X | X | X | X | | | X | |
| 987 | | | | | X | X | | | X | X | | X | | | X |
| 988-3 | X | X | X | | X | X | | | X | X | X | X | X | | |
| 988-4 | | | | | X | X | | | X | X | | X | | | X |

- Mission uses a similar composition, description and packaging as that used by AVL in its products, as shown in the packaging section of this submission.
- Performance equivalence was shown in the following manner:
 - Through a method comparison where results obtained on an equivalent AVL analyzer, calibrated with Mission calibrating products and compared with results obtained on the same analyzer calibrated with AVL calibrating products.
 - Through a precision study where Mission products were installed on an equivalent AVL analyzer and samples were measured minimally twice a day for 9 days.

A summary of the results of these studies follows:

Performance Characteristics:

Precision Data

Precision data were collected from the analysis of three levels of control materials, measured three times within a run, two runs minimally per day for nine days on each AVL analyzer calibrated with all Mission reagents.

Precision Data Table 1 983 AVL Electrolyte Instrument

Three levels of QC Material, Na, K , Cl precision values

| | |
|------------|------------|
| AVL | 983 |
|------------|------------|

Na

| | Mission | | | | | |
|-------|---------|-------|--------|-------|-------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 48 | 117.2 | 1.08 | 113.8 | 120.1 | 0.92% |
| QC2 | 44 | 141.7 | 0.60 | 140.3 | 144.4 | 0.42% |
| QC3 | 48 | 166.9 | 0.82 | 165.3 | 169.4 | 0.49% |

| | |
|------------|------------|
| AVL | 983 |
|------------|------------|

K

| | Mission | | | | | |
|-------|---------|------|--------|------|------|-------|
| Level | N | Mean | Stddev | Min | Max | %CV |
| QC1 | 48 | 1.97 | 0.072 | 1.77 | 2.14 | 3.65% |
| QC2 | 45 | 4.32 | 0.031 | 4.20 | 4.39 | 0.72% |
| QC3 | 48 | 7.10 | 0.089 | 6.88 | 7.48 | 1.26% |

| | |
|------------|------------|
| AVL | 983 |
|------------|------------|

Cl

| | Mission | | | | | |
|-------|---------|-------|--------|-------|-------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 48 | 84.7 | 2.10 | 80.6 | 90.9 | 2.48% |
| QC2 | 45 | 101.2 | 1.15 | 99.0 | 103.6 | 1.13% |
| QC3 | 48 | 133.8 | 0.89 | 129.8 | 135.7 | 0.66% |

Precision Data Table 2 984 AVL Electrolyte Instrument

Three levels of QC Material, Na, K , Ca precision values

| | |
|------------|------------|
| AVL | 984 |
|------------|------------|

Na

| | Mission | | | | | |
|-------|---------|-------|--------|-------|-------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 51 | 117.3 | 1.35 | 114.1 | 120.6 | 1.15% |
| QC2 | 49 | 140.9 | 0.90 | 138.4 | 145.0 | 0.64% |
| QC3 | 51 | 165.1 | 1.82 | 155.1 | 170.8 | 1.10% |

| | |
|------------|------------|
| AVL | 984 |
|------------|------------|

K

| | Mission | | | | | |
|-------|---------|------|--------|------|------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 49 | 2.07 | 0.055 | 1.98 | 2.17 | 2.66% |
| QC2 | 49 | 4.34 | 0.025 | 4.29 | 4.41 | 0.58% |
| QC3 | 51 | 7.03 | 0.049 | 6.87 | 7.11 | 0.70% |

| | |
|------------|------------|
| AVL | 984 |
|------------|------------|

Ca

| | Mission | | | | | |
|-------|---------|------|--------|------|------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 50 | 2.00 | 0.034 | 1.91 | 2.09 | 1.72% |
| QC2 | 48 | 1.10 | 0.020 | 1.03 | 1.14 | 1.85% |
| QC3 | 50 | 0.56 | 0.012 | 0.53 | 0.59 | 2.21% |

Precision Data Table 3 985 AVL Electrolyte Instrument

Three levels of QC Material, Na, K , Li precision values

| | |
|------------|------------|
| AVL | 985 |
|------------|------------|

Na

| | Mission | | | | | |
|-------|---------|-------|--------|-------|-------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 48 | 118.6 | 1.13 | 116.7 | 121.1 | 0.95% |
| QC2 | 47 | 142.4 | 0.61 | 141.5 | 144.7 | 0.43% |
| QC3 | 48 | 166.5 | 0.55 | 165.3 | 167.7 | 0.33% |

| | |
|------------|------------|
| AVL | 985 |
|------------|------------|

K

| | Mission | | | | | |
|-------|---------|------|--------|------|------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 48 | 2.07 | 0.067 | 1.98 | 2.22 | 3.23% |
| QC2 | 47 | 4.38 | 0.061 | 4.32 | 4.75 | 1.40% |
| QC3 | 48 | 7.01 | 0.059 | 6.88 | 7.11 | 0.84% |

| | |
|------------|------------|
| AVL | 985 |
|------------|------------|

Li

| | Mission | | | | | |
|-------|---------|------|--------|------|------|-------|
| Level | N | Mean | StdDev | Min | Max | %CV |
| QC1 | 47 | 0.29 | 0.006 | 0.28 | 0.31 | 2.20% |
| QC2 | 47 | 0.97 | 0.016 | 0.92 | 1.00 | 1.63% |
| QC3 | 48 | 2.13 | 0.041 | 2.02 | 2.21 | 1.90% |

Correlation with AVL Reagents

Correlation data were obtained from human serum samples for Na, K, Cl, Ca, and Li. Serum was first spiked with LiCl to obtain a base Li concentration. Samples were then spiked to yield varying concentrations of each of the measuring analytes. The serum samples were measured on each AVL analyzers calibrated with Mission reagents for 2 runs and Calibrated with AVL reagents for 2 runs each test day.

Linear regression analysis was performed using Mission data as the independent X variable and AVL as the dependent Y variable in the equation $Y = mX + b$

Correlation Data Table 1

Regression Analysis of Mission vs AVL Human Serum Results

$Y = mX + b$ where Y = AVL results, X = Mission results, m = Slope, b = Intercept

| Na | | | | | |
|-----------|----------|--------------|------------------|-----------|--------------|
| | N | Slope | Intercept | R2 | Range |
| 983 | 153 | 0.9859 | 2.13 | 0.9989 | 66 - 178 |
| 984 | 135 | 1.011 | -1.50 | 0.9985 | 66 - 176 |
| 985 | 161 | 1.024 | -3.42 | 0.999 | 67 - 178 |

| K | | | | | |
|----------|----------|--------------|------------------|-----------|--------------|
| | N | Slope | Intercept | R2 | Range |
| 983 | 153 | 0.9777 | 0.12 | 0.9984 | 2.41 - 6.64 |
| 984 | 135 | 1.0034 | 0.03 | 0.9989 | 2.48 - 6.43 |
| 985 | 162 | 1.0094 | -0.02 | 0.9987 | 2.45 - 6.52 |

| | | N | Slope | Intercept | R2 | Range |
|-----|----|----------|--------------|------------------|-----------|--------------|
| 983 | Cl | 151 | 0.9669 | 3.97 | 0.9984 | 52 - 162 |
| 984 | Ca | 134 | 0.9004 | 0.07 | 0.9859 | 0.67 - 2.25 |
| 985 | Li | 132 | 1.0144 | -0.02 | 0.9940 | 0.33 - 2.55 |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

Diamond Diagnostics, Inc.
c/o Ms. Linda M. Studtner
QA/RA Coordinator
Mission Diagnostics
331 Fiske Street
Holliston, MA 01746

Re: k013850
Trade/Device Name: Mission Diagnostic Reagents for AVL 98X Analyzers
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 16, 2001
Received: November 20, 2001

Dear Ms Studtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

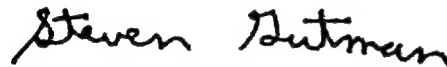
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K013850Device Name: Mission Diagnostic Reagents for AVL 98X Analyzers**Indication For Use:**

The products encompassed by this request are intended for in-vitro diagnostics use and are intended for use in calibrating the electrodes and flushing the sample flow path of the equivalent AVL 98X series Analyzers. AVL Scientific Corp is the Original Equipment Manufacturer (OEM) of the analyzers and the predicate reagents.

| Mission PN | | 98X AVL Instrument Reagent Used On |
|------------|------------|------------------------------------|
| Standard A | AV-BP0936D | 982, 983, 985, 988-3 (Cl, Li) |
| Standard B | AV-BP0937D | 985, 988-3 (Cl, Li) |
| Standard B | AV-BP0442D | 982, 983 |
| Standard C | AV-BP0938D | 985, 988-3 (Li) |
| Standard A | AV-BP1232D | 984, 987, 988-3 (Ca), 988-4 |
| Standard B | AV-BP1218D | 984, 987, 988-3 (Ca), 988-4 |
| Standard A | AV-BP1203D | 986 |
| Standard B | AV-BP1201D | 986 |

Mission reagents are intended to serve as direct replacements to like named products manufactured by AVL.

The products encompassed are to be handled using normal laboratory precautions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of the Device Evaluation (ODE)

Rx ✓

Jean Conner
 (Division Sign-Off)
 Division of Clinical Laboratory
 510(k) Number K013850

(Optional format 3-10-98)